ISO 17025 Accreditation-Transition
The Cyprus Experience

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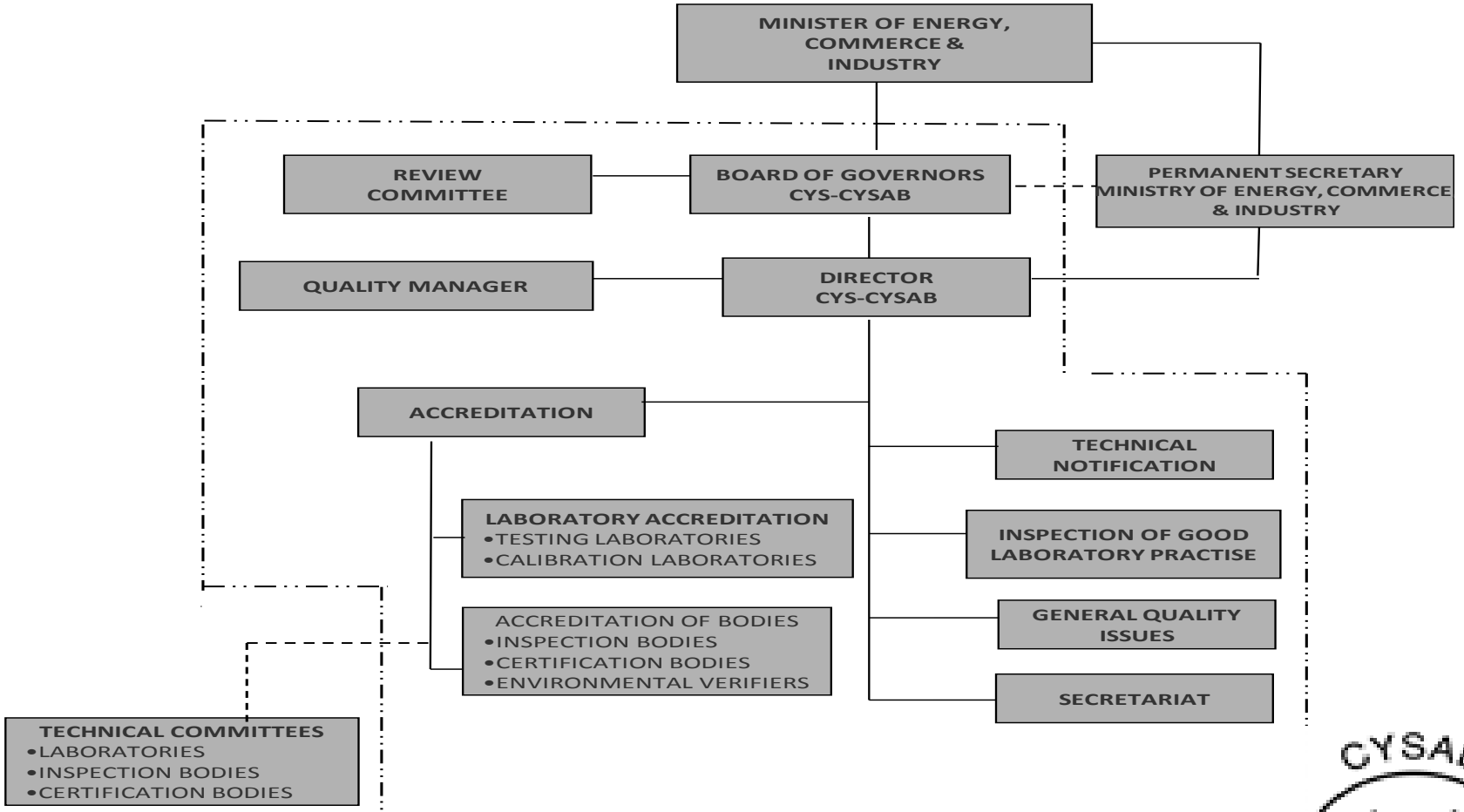
Cyprus Accreditation Body
CYS CYSAB

- Established in 2002
- Operates under the Standardisation, Accreditation and Technical Notification Law (L156(I)/2002)
- The revised **Law 57(I)/2011** established the Cyprus Accreditation Body as the only Accreditation Body that operates in Cyprus as per the requirements of **(EU) no.765/2008**.
- CYS-CYSAB is a non-profit government agency that operates within the Cyprus Ministry of Energy, Industry and Commerce and financed by the Government of Cyprus
- CYS-CYSAB is governed by a 13member Board of Governors which is appointed by the Council of Ministers.

ORGANIZATIONAL STRUCTURE
CYS-CYSAB



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Accreditation Activities

- Testing Laboratories ISO/IEC 17025
- Medical Laboratories ISO 15189
- Calibration Laboratories ISO/IEC 17025
- Inspection Bodies ISO/IEC 17020
- Notified Bodies according to the relevant Standard
- Certification Bodies ISO/IEC 17065, ISO/IEC 17021
- *Monitoring Unit for GLP*

CYS-CYSAB is a signatory to the EA-MLA in the following scopes:

- Testing laboratories ISO/IEC 17025 + Medical Laboratories ISO 15189 (2013)
- Calibration laboratories ISO/IEC 17025 (2014)
- Inspection bodies ISO/IEC 17020 (2013)
- Product Certification Bodies ISO/IEC 17065* (assessment of the extension of Scope in September 2019)

ISO/IEC 17025 Accreditation in Cyprus

Transition to ISO/IEC 17025:2017

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ΔΙΑΠΙΣΤΕΥΣΗ

CYS-CYSAB ISO/IEC 17025 accreditation

- 2006 - first accreditation of Testing Lab ISO/IEC 17025:2005

Scope: Construction Material Testing

- 2011- first accreditation of Calibration Lab ISO/IEC 17025:2005

Scope: Meter Repair & Testing (MRTC)

- End 2014-transfer of Accreditation of ISO/IEC 17025 Testing Labs, as per EU 765/2008, from foreign ABs to CYS-CYSAB

- 2015-transfer of Accreditation of ISO/IEC 17025 Calibration Labs as per EU 765/2008, from foreign ABs to CYS-CYSAB

ACCREDITATION of Testing and Calibration Laboratories ISO/IEC 17025

- Accredited Testing laboratories: 65
- Accredited Calibration Laboratories: 6
- Public and Private Labs
  - Small and Large (incl. Multisites, same legal entity with different sites/locations with same and/or different laboratory activities than the main lab)
- Fixed Scope Accreditation
- Flexible Scope Accreditation (Testing Labs)
- No Sampling in the Scope Accreditation
- No stand-alone sampling Accreditation
- Cross Frontier Accreditation (Testing Labs)
- Four year Accreditation Cycle
- (3 x annual surveillance visits+1 re-assessment visit For renewal)

ISO/IEC 17025 ACCREDITATION

Assessment Criteria-Assessment Tools

- Accreditation Criteria document AC ISO 17025
- OP-08 defines the frequency and the requirements for external quality control participation
- GD-02 defines the requirements for calibration and metrological traceability
- GD-06 defines the requirements for Microbiological Testing Labs Accreditation
- R01-Regulation for Accreditation
- OP-15 Flexible Scope
- OP-16 Cross Border Accreditation
- For the transition CYS-CYSAB's ISO 17025:2017 Laboratory documentation.excel document to be submitted by lab

ISO/IEC 17025 ACCREDITATION

ΚΥΠΡΙΑΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΠΡΟΩΘΗΣΗΣ ΠΟΙΟΤΗΤΑΣ

ΚΥΠΡΙΑΚΟΣ ΦΟΡΕΑΣ ΔΙΑΠΙΣΤΕΥΣΗΣ

ISO 17025 2017-11 Clause	Main content	Documented Information? (Y/N)	ISO 17025 2005-08 Clause	Main content	New? Or Change? (Y/N)	If Change or new: Main Aspect of Change	Laboratory's Documentation
4.1	Impartialitiy	NO	4.1.4 / 4.1.5	Organization	YES	Clearifiying / Risks and opportunities are now implemented	
4.2	Confidentiality	NO	4.1.5 c)	Organization	YES	Clearifying	
5.1	Legal form	NO	4.1.1	Legal form	NO	No significant change	
5.2	Management	NO	4.1.5.a/h	Technical management	YES	More comprehensive term for management is used	
5.3	Range of activities	YES	4.2.2 b	Qualitiy policy	YES	More comprehensive requirements	
5.4	Accordance with standard	NO	4.2.2 e 4.2.6	Qualitiy policy	YES	More comprehensive requirements	
5.5	Internal organsiation	YES	4.1.5 d/e/f	Organisational requirements	NO	No significant change	
5.6	Personnel and other ressources	NO	4.1.5 a/i	Organisational requirements	NO	No substitutes are required anymore	
5.7	Communication / changes	NO	4.1.6 4.2.7	Communication / changes	NO	No significant change	
6.1	Ressource requirements - General	NO	(5.1)	Technical Requirements - General	NEW	Summarising of several aspects	
6.2	Personnel	YES	4.1.5 f.h) 5.2	Organization / Personnel	YES	Monitoring of personnel is new / Evaluation of effectivness is withdrawn	
6.3	Laboratory facilities and environmental conditions	YES	5.3	Accomodation and environmental conditions	YES	Now this clause is also valid for use of external facilities (6.3.5)	
6.4	Equipment	YES	5.5	Equipment	NO	But reference to ISO/IEC 17034 is included	
6.5	Metrological traceability	NO	5.6	Measurment traceability	YES	All equipment used quantified measurement results has to be calibrated but annx A is just informativ	

ISO/IEC 17025 ACCREDITATION
Transition to ISO/IEC 17025:2017

MAIN CHALLENGES:

- Range of Laboratory Activities §*5.3*
- Decision rules and statements of conformity §*7.1.3* & §*7.8.6*
- Sampling §*7.3*
- Actions to address risks§*8.5*

OTHER ISSUES:

- LIMs §7.11
- Metrological traceability of measurement §6.5
- Option B§8.1.3

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Range Of Laboratory Activites

§*5.3 The laboratory shall define and document the range of laboratory activities for which it conforms with this document* ...

What level of detail?

- ISO/IEC 17025:2017 requires a laboratory claiming conformity with the Standard to express a Scope of the competence claimed.
- If a laboratory is involved also in Accreditation this will equal or exceed the Scope agreed with the Accreditation Body
- The laboratory may use the Scope given by the AB but, this should be presented directly and kept up-to-date. It should not be just a link to the AB's website as this would constitute a dependency.
- If it wishes to exceed this Scope then it shall be aware that it may be required to demonstrate evidence of competence

with the ISO/IEC 17025:2017 for the out of Scope Activities

Decision rules and statements of conformity

§7.1.3 Statement of Conformity to a specification or standard.. The specification or standard and the decision rule shall be clearly defined...communicated and agreed with the customer..§7.8.6 Reporting Statements of Conformity

What level of detail in the agreement and in the test report?

Definition In the agreement

- The Decision rule for the test is adequately defined, documented, communicated and agreed with the customer
- If decision rule is not specified in Legislation, Specification or Standard the laboratory shall give information to the customers to understand the risk of false acceptance or false rejection (risk account)
- If the decision rule is inherent in a Standard or Specification of a test agreed with the customer, no extra agreement needed

Decision rules and statements of conformity

Reporting in the test report

- The laboratory shall document the decision rule on test report to provide all information needed with a clear reference to the agreement with the client

- If agreed with the customer (§7.8.1.3), the decision rule on test report can be simplified however, information shall be readily available
- If the Legislation/Standard/Specification contain clear decision rule for the test then a reference is sufficient on test report.
- If not, it shall be clearly stated and take into account the level of risk

Decision rules and statements of conformity

Reporting in the test report (2)

- If a Laboratory's test report includes only the measurement limit and its references for the test but, doesn't report any statement of conformity!

- **The laboratory shall report to the client any decision rule**?
- No, if no decision rule was contracted.
- Where necessary, for the interpretation of the test result, the lab shall report to the client the measurement uncertainty

- **If laboratory declares that does not provide decision rules (or statements of conformity)..**

No documentation required about the decision rule,

it shall be stated in the procedure**.**

Sampling

§5.3 Sampling as laboratory activity- Accredited or not

The laboratory performs sampling:

- Accredited or Not → At the moment there is no lab with sampling in its Scope of Accreditation, or stand-alone Accreditation
- The laboratory shall document if sampling is part of the range of laboratory activities that conform with the Standard
- Sampling not included in the Scope of Accreditation, the sampling is not part of the assessment even if the sampling has influence on uncertainty.
- Clearly marked as “non-accredited” on test reports
- If ‘not-accredited’ sampling included in the range of laboratory activities, lab shall be aware that it may be required to

demonstrate evidence of competence w ISO/IEC 17025:2017

Sampling

§7.3 Sampling

§7.3.1The laboratory shall have a sampling plan and method……

§7.3.2 Sampling method shall describe…§7.3.3 Retain Records of sampling data that forms part of the testing that is undertaken…

The laboratory performs sampling

- If accredited it shall comply with all the above requirements
- If non-accredited it shall have available all the above information in its QMS
- If non-accredited clearly marked as “non-accredited” on test reports
- The requirements for reporting sampling on test reports apply, accredited or not (*§7.8.5)*
- Expected that there is going to be available information

on theMoU from sampling (*§7.8.5f)*

Sampling

<u>The laboratory not responsible for the sampling stage</u>

The sample has been provided by the customer

- The laboratory shall document the customer has been informed of the sampling requirements (§*7.3.1*- §*7.3.3)*
- Clearly marked as “non-accredited” on test reports
- Data provided by customer shall be clearly identified on the test report (e.g. Sample provided by the customer , results apply as sample received §*7.8.2.2)*

Actions to address Risk

§8.5.1 The laboratory shall consider the risks..associated with the laboratory activities…

§8.5.2..shall plan actions ..how to integrate into its MS and evaluate their effectiveness

What is the level of detail/documentation that is expected from lab?

- The laboratory shall document the risks and opportunities considered related to their activities. Lab could choose their own risk model..
- It shall take in mind aspects related to laboratory activities, Scope of Accreditation
- Risk consideration could include what should be done, who will be responsible, who will be managing the process, time plan and result. Plan must include significance of the risk.

Actions to address Risk

- **Level of details:**
- depends on methodology used by the lab.
- are linked to the maturity of the lab in risk management and scope of accreditation.
- Records for action plan, the risk identification, actions to allow a periodic evaluation/status to evaluate the effectiveness/integration & implementation of the actions into QMS.

- Sometimes, in small labs, management review can be sufficient if there is short frequency and all persons-come on meeting.

- **NOTE**: Generally, Management Review is to inform the top management, about the results of risk identification and to decide provision of recourses needed and/or need for changes in order to ensure effectiveness of the actions.

Actions to address Risk

Assessing risk and opportunities e.g. principles, tools, expectations

- Main expectation is that laboratory has risk based thinking approach, and complies § 8.5.
- Risks and opportunities have been addressed according to risk plan.
- Consideration of the Scope of Accreditation
- Assessing the records for action plan, risk identification, actions to allow a periodic evaluation/status to evaluate the effectiveness/integration & implementation of the actions into QMS.
- Risks normally are linked to the maturity of the lab in risk management.
- If there is a proof that actions are not implemented and affecting the validity of results, then a NCs shall be addressed.
- If the assessor finds that a risk is not identified by the lab if a risk is not properly assessed, a finding shall be raised

OTHER ISSUES

- **Laboratory Information Management LIMS**

▪**What is required** from a lab ?

-The lab has to validate/verify the LIMS, as per § 7.11.2

-LIMS shall be part of the QMS of the lab (§6.4) and personnel to be trained/authorised to access (§ 6.2)

-Requirements § 7.11.3, § 7.11.5 shall be fulfilled

▪If LIMS is **maintained and managed by an external provider?**

-The laboratory shall be assessed how it manages the external provider (**§** 6.6.2); the lab has the responsibility that the requirements of 17025 are in the agreement.

-Requirements are communicated to the provider (§ 6.6.3)

-It is assessed that the agreement is fulfilled (§ 7.11.4).

OTHER ISSUES

- **Management system Option B**

- ***§8.1.3*** *A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.*

- **What is required** from such a lab ?
- It is expected that the lab shall document conformity with the requirements of ISO/IEC 17025:2017 **§ 8.2-8.9**

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Thanks for your attention!...